510(k) SUMMARY K081982

Itamar Medical Ltd
Watch PAT200S-2 System AUG 14 2008

Applicant's Name:

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Date Prepared:

July 11, 2008

Trade Name:

Watch-PAT 200S-2 ("WP200S-2")

Common Name:

Ventilatory Effort Recorder

Classification:

21 CFR 868.2375
Class:II
MNR (Ventilatory Effort Recorder).

Classification Name: Breathing Frequency Monitor

Medical Specialty: Anesthesiology

Predicate Devices:

- Watch-Pat100S-2 ("WP100S-2") (Itamar Ltd), cleared under K080427; product code MNR (ventilatory effort recorder).
- Watch-Pat200i ("WP200i") (Itamar Ltd), cleared under K081037; product code MNR (ventilatory effort recorder).

Device Description:

The WATCH-Pat200-2 System (WP200S-2) is a non-invasive home care device for use with patients suspected to having sleep related breathing disorders. The WP200S-2 is a diagnostic aid for the detection of sleep related breathing disorders [Respiratory disturbance index (RDI), apnea – hypopnea index (AHI)] and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake) based on Peripheral Arterial Tonometry (PAT); a non-invasive technology. a, based on Peripheral Arterial Tonometry (PAT); a non-invasive technology.

The WP200S-2 System is a compact version of the WP100S-2 System, both consist of: (1) a finger PAT probe, which is used to detect the PAT signal; (2) an embedded pulse oximeter using a second probe that is attached to another finger for measuring blood oxygen saturation; (3) an embedded actigraph which is used to determine periods of sleep based on the motion of the wrist; (4) Electronics which include a controller that records the information supplied by the PAT finger probe, oximeter, and actigraph; (5) the device software; and (6) a power supply.

The device is worn on the wrist, and continuously measures the relative state of the vasomotor activity in the distal part of the finger, by a finger-mounted probe based on a plethysmographic method. The measured signal is acquired from a self contained, opto-pneumatic sensor.

Intended Use:

The Watch-PAT200S-2 (WP200S-2) device is a non-invasive home care device for use with patients suspected to have sleep related breathing disorders. The WP200S-2 is a diagnostic aid for the detection of sleep related breathing disorders and sleep staging (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake). The WP200S-2 generates a peripheral arterial tonometry ("PAT") Respiratory Disturbance Index ("PRDI"), Apnea-Hypopnea index ("PAHI") and PAT sleep staging identification (PSTAGES). The WP100S-2's PSTAGES provides supplemental information to its PRDI/PAHI. The WP100S-2's PSTAGES is not intended to be used as the sole or

primary basis for diagnosing any sleep related breathing disorder, prescribing treatment, or determining whether additional diagnostic assessment is warranted.

The WP100S-2 is not indicated for children less than 17 years old.

Performance Data & Substantial Equivalence:

The WP200S-2 System is substantially equivalent in all aspects, including technological characteristics, mode of operation, performance characteristics, intended use, etc., to the commercially available WP100S-2 System, cleared under K080427 and in respect of its hardware is also substantially equivalent to the WP200i System cleared under K081037.

The principle changes between the WP100S-2 and the WP200S-2 systems include minor hardware modifications that were made to the controller components to enable more compact design and lower power consumption. The hardware of the WP200S-2 system is identical to the hardware of the WP200i, both are compact versions of the Watch Pat system. This WP200i/WP200S-2 hardware was subjected to the following testing (K081037):

- Electrical and electromagnetic testing
- Electronics design verification test
- Performance testing demonstrating the accuracy of the captured signals and device's reproducibility

The software of the WP200S-2 is the same software as the WP100S-2, allowing for the detection of sleep related breathing disorders and presentation of both the PRDI and PAHI indices and PAT sleep staging identification; PSTAGES (Rapid Eye Movement (REM) Sleep, Light Sleep, Deep Sleep and Wake). A comprehensive software verification and validation activities were conducted to ensure that the software meets all software requirement specifications.

Based on the design verification and validation processes, performed as a result of risk analysis assessment, Itamar Medical Ltd. believes that the WP200S-2 System is substantially equivalent to the cleared WP100S-2 System without raising new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Itamar Medical Limited
C/O Mr. Jonathan S. Kahan
Regulatory Counsel
Hogan & Hartson L.L.P
555 Thirteenth Street, NW
Washington, DC 20004

AUG 14 2008

Re: K081982
Trade/Device Name: Watch-PAT200S-2 (WP200S-2)
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: July 11, 2008
Received: July 11, 2008

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081982

Device Name:

Indications for Use:

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The WP200S-2 is not indicated for children less than 17 years old.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081982

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)